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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO	
10/019,249	06/05/2002	Kozo Aoki	Q67718	1284	
23373	7590 05/14/2003				
SUGHRUE MION, PLLC			EXAMINER		
2100 PENNSYLVANIA AVENUE, N.W. WASHINGTON, DC 20037			MORRIS, PATRICIA L		
			ART UNIT	PAPER NUMBER	
			1625		
			DATE MAILED: 05/14/2003		

Please find below and/or attached an Office communication concerning this application or proceeding.

A	pplication No.	Applicant(s)		
Office Action Summary	10/019,249	Aoki et		
Office Action Summary	xaminer		Group Art Unit	
	- KMaris		1625	
—The MAILING DATE of this communication appears or	n the cover sheet b	eneath the co	rrespondence add	iress
eriod f r Reply				
SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EX F THIS COMMUNICATION.	KPIRE three	MONTH(S)	FROM THE MAIL!	NG DATE
<ul> <li>Extensions of time may be available under the provisions of 37 CFR 1.136(from the mailing date of this communication.</li> <li>If the period for reply specified above is less than thirty (30) days, a reply with In NO period for reply is specified above, such period shall, by default, expirations for reply within the set or extended period for reply will, by statute, cannot be such as a superior of the provisions of 37 CFR 1.136(from the provisions o</li></ul>	ithin the statutory minime SIX (6) MONTHS from	num of thirty (30) on the mailing date	lays will be considered of this communication	timely.
tatus				
Responsive to communication(s) filed on 3-18-03				•
This action is FINAL.				
Since this application is in condition for allowance except for for accordance with the practice under Ex parte Quayle, 1935 C.I.			the merits is close	e <b>d</b> in
isp sition of Claims				
Claim(s) 1-12, 14-18, 20 and 21  Of the above claim(s) 14-18 and 20		is/are p	ending in the applic	cation.
Of the above claim(s) 14 - 18 and 20	is/are w	is/are withdrawn from consideration.		
□ Claim(s)	!= /=====	llowed		
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U. S. Patent and Trademark Office PTO-326 (Rev. 9-97)

Part of Paper No.

Application/Control Numer: 10/019,249

Art Unit: 1625

#### **DETAILED ACTION**

Claims 1-12 and 21 are under consideration in this application.

Claims 14-18 and 20 remain held withdrawn from consideration as being drawn to nonelected subject matter 37 CFR 1.142(b).

#### Election/Restriction

Again, this application has been examined with respect to the elected compound and expanded to include a genus wherein A is methylene, L is C<sub>4</sub> - C<sub>8</sub> alkylene, X is O, S or CH<sub>2</sub>, and m is 0 or 1, as set forth in claim 1, exclusively.

### Claim Rejections - 35 USC § 103

The rejection under 35 U.S.C. 103(a) over Gregory et al. is hereby withdrawn in view of applicants' certified English translation.

Claims 1-12 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Giani et al.(US 4,971,980) for the reasons set forth in Paper no. 11.

Again, Giani et al. teach analogous compounds that differ by homology. For example, 2-(4-piperidin-1-ylbutyl)benzimidazole in example 4 of Giani differs only in having a C<sub>4</sub> alkylene chain. The prior art compounds differ from the compounds claimed herein as alkyl homologs of the claimed compounds. For example, the instant compounds wherein n is 4 are the next adjacent homologs of the compounds of Giani et al. One having ordinary skill in the art would have been motivated by the disclosure of the prior art compounds to arrive at other compounds within the claimed genus. The motivation to make these compounds is their close structural similarities to the disclosed compound.

Application/Control Number: 10/019,249

Art Unit: 1625

Note that the disclosed compounds of the references have pharmaceutical activity, thus the skilled artisan would expect such structurally similar compounds to possess similar properties.

Applicants have failed to argue the reference of Giani et al. No unexpected or unbvious results are noted for the claimed compounds *vis-à-vis* the prior art compounds of Giani et al.

## Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 7, 10, 12 and 21 are rejected under 35 U.S.C. 112, first paragraph, as containing subject which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Again, applicants claim all acyl radicals in  $R^2$ ,  $R^{12}$  and  $R^{13}$  in clams 1, 7, 12 and 21.

Applicants' exemplification cannot be seen to provide adequate representative support for such a claim.

The expressions "R³ and R¹³ represents one or more....nitrogen atom", "phenyl .... Which may be substituted" and "acyl" are employed with considerable abandon throughout claims 1, 7, 10, 12 and 21 with no indication given as to what the substituents or acyl groups really are.

Application/Control Number: 10/019,249

Art Unit: 1625

One should be able, from a reading of the claims, determine what that claim does or does not encompass.

Why? Because that claim precludes others from making, using, or selling that compound for 20 years. Therefore, one must know what compound is being claimed.

The unknown substituents and acyl groups are so broad that they cause the claim to have a potential scope of protection beyond that which is justified by the specification disclosure.

The written description is considered inadequate here in the specification.

Conception of the intended substituents and acyl groups should not be the role of the reader. Applicants should, in return for a 20 year monopoly, be disclosing to the public that which they know as an actual demonstrated fact. The disclosure should not be merely an invitation to experiment. This is a 35 USC 112, first paragraph. If you (the public) find that it works, I claim it, is not a proper basis of patentability. In re Kirk, 153 USPQ 48, at page 53.

Contra to applicants' arguments in the instant response filed March 18, 2003, one cannot tell from a simple reading of the claim what is being claimed. One must first conceive of the substituents and acyl groups. Then one must, by preparing the compound himself, determine if the substituents and acyl group works or not. Where is the specific claiming and distinctly pointing out? How can applicants regard as their invention inexact concepts? The breadth of which they could not have possibly checked out with representative exemplification. The terms are not finite.

Applicants are claiming a compound of the formula. Pure chemistry, a compound.

Not a resin of general property ranges, but a pure compound. That compound used for

Application/Control Numer: 10/019,249

Art Unit: 1625

any purpose is taken from the public in a 20-year monopoly to applicants. Then, the public is entitled to know what compound they cannot use. Yet, the claim is not specific to that compound. The public cannot tell what they may not use. How is a claim of the instant breadth defensible in an infringement action?

As applied to pure compounds, <u>In re Cavallito and Gray</u>, 134 USPQ 370, and <u>In re Sus and Schaefer</u>, 134 USPQ 301, are considered to set the proper applicable standard of required definiteness and support.

#### Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Art Unit: 1625

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ms. Morris whose telephone number is (703) 308-4533.

plm

May 13, 2003